

§ 186.1771

with a slight tallow-like odor. Commercially, sodium oleate is made by mixing and heating flaked sodium hydroxide and oleic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging and as a component of lubricants with incidental food contact in accordance with § 178.3570 of this chapter, with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1771 Sodium palmitate.

(a) Sodium palmitate ($C_{16}H_{31}O_2Na$, CAS Reg. No. 408-35-5) is the sodium salt of palmitic acid (hexadecanoic acid). It exists as a white to yellow powder. Commercially, sodium palmitate is made by mixing and heating flaked sodium hydroxide and palmitic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1797 Sodium sulfate.

(a) Sodium sulfate (Na_2SO_4 , CAS Reg. No. 7757-82-6), also known as Glauber's salt, occurs naturally and exists as colorless crystals or as a fine, white crystalline powder. It is prepared by the neutralization of sulfuric acid with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging, and cotton and cotton fabric used for dry food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980]

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§ 186.1839 Sorbose.

(a) Sorbose (L-sorbose, sorbinose) ($C_6H_{12}O_6$, CAS Reg. No. 87-79-6) is an orthorhombic, bisphenoidal crystalline ketohexose. It was originally identified in the juice of mature berries from the mountain ash (*Sorbus aucuparia*) where it occurs as the result of microbial oxidation of sorbitol. It also occurs naturally in other plants. Sorbose can be synthesized by the catalytic hydrogenation of glucose to D-sorbitol. The resulting sorbitol can be oxidized by *Acetobacter xylinum* or by *Acetobacter suboxydans*.

(b) The ingredient is used or intended for indirect food use as a constituent of cotton, cotton fabrics, paper, and paperboard in contact with dry food.

(c) The ingredient migrates to food at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11698, Mar. 21, 1978, as amended at 48 FR 48457, Oct. 19, 1983]

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

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Sec.

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AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14659, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 189 appear at 61 FR 14482, Apr. 2, 1996, and 66 FR 56035, Nov. 6, 2001.

Subpart A—General Provisions

§ 189.1 Substances prohibited from use in human food.

(a) The food ingredients listed in this section have been prohibited from use in human food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Use of any of these substances in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully be used in human food. No substance may be used in human food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, pursuant to part 10 of this chapter, and will be published for comment if it contains reasonable grounds.

[42 FR 14659, Mar. 15, 1977, as amended at 54 FR 24899, June 12, 1989]

Subpart B—Substances Generally Prohibited From Direct Addition or Use as Human Food

§ 189.110 Calamus and its derivatives.

(a) Calamus is the dried rhizome of *Acorus calamus* L. It has been used as a flavoring compound, especially as the oil or extract.

(b) Food containing any added calamus, oil of calamus, or extract of calamus is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of May 9, 1968 (33 FR 6967).

(c) The analytical method used for detecting oil of calamus (β -asarone) is in the "Journal of the Association of Official Analytical Chemists," Volume 56, (Number 5), pages 1281 to 1283, September 1973, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, also from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 47 FR 11855, Mar. 19, 1982; 54 FR 24899, June 12, 1989]

§ 189.113 Cinnamyl anthranilate.

(a) The food additive cinnamyl anthranilate ($C_{16}H_{15}NO_2$, CAS Reg. No. 87-29-6) is the ester of cinnamyl alcohol and anthranilic acid. Cinnamyl anthranilate is a synthetic chemical that has not been identified in natural products at levels detectable by available methodology. It has been used as a flavoring agent in food.

(b) Food containing any added cinnamyl anthranilate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 23, 1985.

[50 FR 42932, Oct. 23, 1985]

§ 189.120

§ 189.120 Cobaltous salts and its derivatives.

(a) Cobaltous salts are the chemicals, $\text{CoC}_4\text{H}_6\text{O}_4$, CoCl_2 , and CoSO_4 . They have been used in fermented malt beverages as a foam stabilizer and to prevent "gushing."

(b) Food containing any added cobaltous salts is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 12, 1966 (31 FR 8788).

§ 189.130 Coumarin.

(a) Coumarin is the chemical 1,2-benzopyrone, $\text{C}_9\text{H}_6\text{O}_2$. It is found in tonka beans and extract of tonka beans, among other natural sources, and is also synthesized. It has been used as a flavoring compound.

(b) Food containing any added coumarin as such or as a constituent of tonka beans or tonka extract is deemed to be adulterated under the act, based upon an order published in the FEDERAL REGISTER of March 5, 1954 (19 FR 1239).

(c) The analytical methods used for detecting coumarin in food are in sections 19.016-19.024 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 189.135 Cyclamate and its derivatives.

(a) Calcium, sodium, magnesium and potassium salts of cyclohexane sulfamic acid, $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})_2\text{Ca}$, $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})\text{Na}$, $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})_2\text{Mg}$, and $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})\text{K}$. Cyclamates are synthetic chemicals having a sweet taste 30 to 40 times that of sucrose, are not found in natural products at levels detectable by the official methodology, and have been used as artificial sweeteners.

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(b) Food containing any added or detectable level of cyclamate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 21, 1969 (34 FR 17063).

(c) The analytical methods used for detecting cyclamate in food are in sections 20.162-20.172 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 189.140 Diethylpyrocarbonate (DEPC).

(a) Diethylpyrocarbonate is the chemical pyrocarbonic acid diethyl ester, $\text{C}_6\text{H}_{10}\text{O}_5$. It is a synthetic chemical not found in natural products at levels detectable by available methodology and has been used as a ferment inhibitor in alcoholic and nonalcoholic beverages.

(b) Food containing any added or detectable level of DEPC is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 2, 1972 (37 FR 15426).

§ 189.145 Dulcin.

(a) Dulcin is the chemical 4-ethoxyphenylurea, $\text{C}_9\text{H}_{12}\text{N}_2\text{O}_2$. It is a synthetic chemical having a sweet taste about 250 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of dulcin is deemed to be adulterated in violation of the act, based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting dulcin in food are in sections 20.173-20.176 of the "Official Methods of

Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 189.155 Monochloroacetic acid.

(a) Monochloroacetic acid is the chemical chloroacetic acid, $C_2H_3ClO_2$. It is a synthetic chemical not found in natural products, and has been proposed as a preservative in alcoholic and nonalcoholic beverages. Monochloroacetic acid is permitted in food package adhesives with an accepted migration level up to 10 parts per billion (ppb) under § 175.105 of this chapter. The official methods do not detect monochloroacetic acid at the 10 ppb level.

(b) Food containing any added or detectable level of monochloroacetic acid is deemed to be adulterated in violation of the act based upon trade correspondence dated December 29, 1941 (TC-377).

(c) The analytical methods used for detecting monochloroacetic acid in food are in sections 20.067-20.072 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 189.165 Nordihydroguaiaretic acid (NDGA).

(a) Nordihydroguaiaretic acid is the chemical 4,4'-(2,3-dimethyltetramethylene) dipyrocatechol, $C_{18}H_{22}O_4$. It occurs naturally in the resinous exudates

of certain plants. The commercial product, which is synthesized, has been used as an antioxidant in foods.

(b) Food containing any added NDGA is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 11, 1968 (33 FR 5619).

(c) The analytical method used for detecting NDGA in food is in section 20.008(b) of the "Official Methods of Analysis of the Association of Official Analytical Chemists International," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§ 189.175 P-4000.

(a) P-4000 is the chemical 5-nitro-2-n-propoxyaniline, $C_9H_{12}N_2O_3$. It is a synthetic chemical having a sweet taste about 4000 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of P-4000 is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting P-4000 in food are in sections 20.177-20.181 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§ 189.180

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§ 189.180 Safrole.

(a) Safrole is the chemical 4-allyl-1,2-methylenedioxy-benzene, $C_{10}H_{10}O_2$. It is a natural constituent of the sassafras plant. Oil of sassafras is about 80 percent safrole. Isosafrole and dihydrosafrole are derivatives of safrole, and have been used as flavoring compounds.

(b) Food containing any added safrole, oil of sassafras, isosafrole, or dihydrosafrole, as such, or food containing any safrole, oil of sassafras, isosafrole, or dihydrosafrole, e.g., sassafras bark, which is intended solely or primarily as a vehicle for imparting such substances to another food, e.g., sassafras tea, is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 3, 1960 (25 FR 12412).

(c) The analytical method used for detecting safrole, isosafrole and dihydrosafrole is in the "Journal of the Association of Official Analytical Chemists," Volume 54 (Number 4), pages 900 to 902, July 1971, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 42 FR 56729, Oct. 28, 1977; 47 FR 11855, Mar. 19, 1982; 54 FR 24900, June 12, 1989]

§ 189.190 Thiourea.

(a) Thiourea is the chemical thiocarbamide, CH_4N_2S . It is a synthetic chemical, is not found in natural products at levels detectable by the official methodology, and has been proposed as an antimycotic for use in dipping citrus.

(b) Food containing any added or detectable level of thiourea is deemed to be adulterated under the act.

(c) The analytical methods used for detecting thiourea are in sections 20.115-20.126 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980),

which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§ 189.191 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human food as propellants in self-pressurized containers is prohibited as provided by § 2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]

Subpart C—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

§ 189.220 Flectol H.

(a) Flectol H is the chemical 1,2-dihydro-2,2,4-trimethylquinoline, polymerized, $C_{12}H_{15}N$. It is a synthetic chemical not found in natural products, and has been used as a component of food packaging adhesives.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 7, 1967 (32 FR 5675).

[42 FR 14659, Mar. 15, 1977, as amended at 58 FR 17099, Apr. 1, 1993]

§ 189.240 Lead solders.

(a) Lead solders are alloys of metals that include lead and are used in the construction of metal food cans.

(b) Food packaged in any container that makes use of lead in can solder is deemed to be adulterated in violation of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the FEDERAL REGISTER of June 27, 1995.

[60 FR 33109, June 27, 1995]

§ 189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.

(a) Mercaptoimidazoline and 2-mercaptoimidazoline both have the molecular formula $C_3H_6N_2S$. They are synthetic chemicals not found in natural products and have been used in the production of rubber articles that may come into contact with food.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of November 30, 1973 (38 FR 33072).

§ 189.280 4,4'-Methylenebis (2-chloroaniline).

(a) 4,4'-Methylenebis (2-chloroaniline) has the molecular formula, $C_{13}H_{12}Cl_2N_2$. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesives and polyurethane resins.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 2, 1969 (34 FR 19073).

§ 189.300 Hydrogenated 4,4'-isopropylidene-diphenolphosphite ester resins.

(a) Hydrogenated 4,4'-isopropylidene-diphenolphosphite ester resins are the condensation product of 1 mole of triphenyl phosphite and 1.5 moles of hydrogenated 4,4'-isopropylidene-diphenol such that the finished resins have a molecular weight in the range of 2,400 to 3,000. They are synthetic chemicals not found in natural products and have been used as antioxidants and as stabilizers in vinyl chloride polymer resins when such polymer resins are used in the manufacture of rigid vinyl chloride polymer bottles.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the FEDERAL REGISTER of September 9, 1987 (52 FR 33929).

[54 FR 7188, Feb. 17, 1989]

§ 189.301 Tin-coated lead foil capsules for wine bottles.

(a) Tin-coated lead foil is composed of a lead foil coated on one or both sides with a thin layer of tin. Tin-coated lead foil has been used as a capsule (i.e., as a covering applied over the cork and neck areas) on wine bottles to prevent insect infestation, as a barrier to oxygen, and for decorative purposes. Information received by the Food and Drug Administration establishes that the use of such a capsule on wine bottles may reasonably be expected to result in lead becoming a component of the wine.

(b) The capping of any bottles of wine after February 8, 1996, with a tin-coated lead foil capsule renders the wine adulterated and in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act because lead from the capsule, which is an unsafe food additive within the meaning of section 409 of the act, may reasonably be expected to become a component of the wine.

[61 FR 4820, Feb. 8, 1996]

PART 190—DIETARY SUPPLEMENTS**Subpart A [Reserved]****Subpart B—New Dietary Ingredient Notification**

Sec.

190.6 Requirement for premarket notification.

AUTHORITY: Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 342, 350b, 371).

SOURCE: 62 FR 49891, Sept. 23, 1997, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 190 appear at 66 FR 56035, Nov. 6, 2001.

Subpart A [Reserved]**Subpart B—New Dietary Ingredient Notification****§ 190.6 Requirement for premarket notification.**

(a) At least 75 days before introducing or delivering for introduction into interstate commerce a dietary